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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/450,217	11/29/99	ERDMANN	P 8265-296-999

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EXAMINER	
LUKTON, D	
ART UNIT	**PAPER NUMBER**
1653	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/450,217	Applicant(s) Erdmann
	Examiner David Lukton	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 1, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above, claim(s) *14-22* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Pursuant to the directives of paper No. 10 (filed 6/1/01), claims 1, 6, 9, 11, 14-22 have been amended. Claims 1-22 remain pending.

Claims 14-22 remain withdrawn from consideration, nothwithstanding the amendments to these claims. These claims are drawn to processes which require steps beyond those required of the process that was presented at the time of the first Office action. Nevertheless, in the event that one or more claims is found allowable, the possibility of rejoining one or more of claims 14-22 is not precluded.

Applicants' arguments filed 6/1/01 have been considered and found not persuasive with regard to the §103 rejection.

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 9, 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The cited claims do not require isolation of the GMP. The question then arises, how does one use the GMP if it is never isolated? If it is present in a mixture with other materials,

and present in a container from which it is never removed, how does one proceed? The specification provides no guidance in this regard. It is suggested that the claims be amended to require isolation (or recovery) of the GMP.

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Claims 1-13 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- None of claims 1, 6 or 9 requires isolation of the GMP. Accordingly, the claims are indefinite as to the process steps. It is suggested that the claims be amended to require isolation (or recovery) of the GMP. Claim 12 also fails to recite isolation or recovery of the GMP. At first glance it would appear that claim 12 recites isolation of the GMP. But in comparing claim 13 with claim 12, it is evident that claim 12 does not actually require isolation of the GMP per se, but rather requires isolation of a solution containing it. Of course, there is no prohibition under §112 second paragraph against an applicant claiming a method of recovering a *solution* of GMP. But if the claim is going to recite extraction of GMP (rather than a solution of it), then the claim should provide the means to achieve this objective.

- In claim 3, the term "sweet whey" lacks antecedent basis.

- In claims 3 and 4, the phrase "cation removal step" lacks antecedent basis.

- Claim 4 mandates the addition of calcium ions, presumably after the deionization step. However, this is not required by claim 1. Accordingly, the scope of claim 1 should be expanded to explicitly recite this possibility, or else claim 4 should be made independent.

- Claim 5 mandates treating the alkaline resin with an alkaline solution prior to contacting the lactic raw material with the resin. However, this is not required by claim 1. Accordingly, the scope of claim 1 should be expanded to explicitly recite this possibility, or else claim 5 should be made independent.

- Claim 10 mandates a spray drying step which is not required or suggested by claim 9. Accordingly, the scope of claim 9 should be expanded to explicitly recite this possibility, or else claim 10 should be made independent. A related issue concerns the presence of the term "the treated material" in claim 10. The phrase at issue ("the treated material") presumably refers to the product that results from spray drying of the "treated liquid material". Accordingly, following a spray drying proceduure, one no longer has a "liquid material". Correction or clarification is required.

- Claim 12 mandates a desorbing and washing step which is not required or suggested by claim 1. Accordingly, the scope of claim 1 should be expanded to explicitly recite this possibility, or else claim 12 should be made independent.

- Claim 12 is somewhat unclear. The second recited step is one of "separating the GMP from the resin", and the third recited step is one of "desorbing the GMP from the resin". The question is, once the GMP has been separated from the resin, is it not the case that one then has GMP which is separate from the resin, and resin which is separate from the GMP...? And if one has resin which no longer has any GMP bound to it, how can one "desorb" GMP from it?

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The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-3, 5-13 are rejected under 35 U.S.C. §103 as being unpatentable over Shimatani

(USP 5,434,250).

As indicated previously, Shimatani teaches (beginning at col 2, line 67) a process of obtaining GMP by passing desalted whey, at acidic pH, through a cation exchanger. Additionally, claim 5 of the patent (col 6, line 23+) teaches a process of obtaining GMP by passing whey, at acidic pH, through a cation exchanger, and then employing the further step of ultrafiltration.

Applicants have traversed by arguing that the reference teaches a process for obtaining sialic acids, rather than GMP. However, the disclosure is replete with references to GMP. It may be true that the reference does not emphasize the desirability of recovering, and subsequently using the GMP, but the reference teaches a process that results in the separation of GMP from the other components.

In further traversing, prosecution would be advanced if applicants would be very specific in explaining exactly which step(s) the reference fails to teach, rather than merely asserting that the processes are "quite different". In addition, it is noted that Saito (*J Dairy Sci* **74**, 2831, 1991) separated sialo-caseinoglycopeptide from asialo-caseinoglycopeptide using affinity chromatography. If applicants believe that their process is directed to the use of the asialo-GMP, applicants should point out the location in the specification where this is discussed.

The rejection is maintained.

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Claims 1-3 and 5-13 are rejected under 35 U.S.C. §103 as being unpatentable over Shimatani (USP 5,434,250) in view of Marshall (*Food Research Quarterly* **51**, 1991, reference "AL" on the IDS)

The teachings of Shimatani were indicated previously. While Shimanti discloses a process which results in the production of GMP, the reference does not emphasize the value of GMP as a nutritional or food product. Marshall discloses that GMP is useful as a nutritional or food product. Marshall does not teach the claimed process.

When the claims were rejected over Shimatani (taken by itself) applicants argued that the reference fails to provide motivation to isolate the GMP. That motivation is provided by Marshall.

Thus, the claims are rendered obvious.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600